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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,283	10/12/2001	Wenbin Dang	GPT-024.01	1639

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EXAMINER

AZPURU, CARLOS A

ART UNIT PAPER NUMBER

1615

DATE MAILED: 02/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/976,283

Applicant(s)

DANG ET AL.

Examiner

Carlos A. Azpuru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 25-35, 42 and 45-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 15, 16, 19, 23, 28, 36-41 and 60 is/are rejected.
- 7) ☒ Claim(s) 3-14, 17, 18, 20-22, 24-27, 43 and 44 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

DETAILED ACTION

Receipt is acknowledged of the amendment, request for reconsideration and information disclosure statement filed 11/03/03. It is noted that none of the disclosed documents have been enclosed. These should be provided along with a properly filed PTOL-1449.

Election/Restrictions

Applicant's remarks concerning the elected claims have been noted. However, claims 29-35, 42 and 45-59, while dependent upon claim 1, do not pertain to elected structural species Vi. Therefore, the claims will remain withdrawn from consideration.

The rejection under 35 USC 112, second paragraph is withdrawn in view of applicant's amendment of the claims. The rejection under 35 USC 103(a) is withdrawn in view of applicant's remarks concerning co-ownership of the patent. A rejection under the judicially created doctrine of obviousness-type double patenting will be cited in its place.

Applicant's arguments filed 11/03/2003 have been fully considered but they are not persuasive.

Regarding the rejection under 35 USC 102(b) over Wen et al, applicant is correct regarding the basis of the rejection given that the reference predates the effective priority date by less than a year. The basis of this rejection has been modified to 35 USC 102(a).

As for what the reference itself discloses, applicant is reminded that the claims set out a composition. The intended use of the composition for inhibiting growth of a neoplasm is not given patentable weight. As such, the claims are clearly anticipated by Wen et al.

Regarding the rejection

The following rejection has been modified to reflect the rejection over the priority date:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2, 15, 16, 23, and 28 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Wen et al.

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Wen et al disclose a biocompatible polymer having phosphate-based linkages and one or more radiosensitizers (see introduction as well as materials and methods). The composition may have up to 25% loading level, and may be in the form of microspheres (see page 66, column 2, paragraph 3). Delivery may be for a period of about 50 days (see Figure 1). The instant claims are anticipated by Wen et al.

The following rejection is made in view of applicant's statement of co-ownership of the Mao patent:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,2, 19, 36-41 and 60 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-260 of U.S.

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Patent No. 6,166,173 (Mao et al). Although the conflicting claims are not identical, they are not patentably distinct from each other because Mao et al disclose the use of a biodegradable polymer of structure VI. Radiosensitizers are disclosed for inclusion into this composition at col. 20, lines 57-65. Like other bioactives disclosed for incorporation into the claimed polymeric structure, radiosensitizers may be incorporated at between about 1% to about 65% (see col. 21, lines 6-10). Therefore, it would have been well within the skill of the ordinary practitioner to claim the instant polymer system for delivery of radiosensitizers for their art recognized purpose. Further, the ordinary practitioner would have expected similar therapeutic results in the treatment of tumors given the disclosure of Mao et al. The addition of instructions for this composition in order to form a kit is a skill within the ordinary skill of any practitioner, given the clear teaching by Mao et al to use the claimed composition for the same art recognized purpose/There are no unusual and/or unexpected results which would rebut prima facie obviousness. As such, the instant drug delivery system for delivery of radiosensitizers and a kit used for that same purpose would have been obvious given the disclosure of Mao et al which sets out the instant monomeric units which are polymerized for delivery of the same radiosensitizing agents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

ca


CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500